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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/769,574	01/29/2004	Bret Berner	66631.8001.US01	8962
79975	7590	07/07/2009	EXAMINER	
King & Spalding LLP			HOLT, ANDRIAE M	
P.O. Box 889				
Belmont, CA 94002-0889			ART UNIT	PAPER NUMBER
			1616	
			MAIL DATE	DELIVERY MODE
			07/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/769,574	BERNER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 June 2009.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 29 is/are withdrawn from consideration.
- 5) Claim(s) 18-20 and 22-28 is/are allowed.
- 6) Claim(s) 1,2 and 11-14 is/are rejected.
- 7) Claim(s) 3-10 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

This Office Action is in response to Applicant's after final amendment filed June 16, 2009. Claims 1-20 and 22-29 are pending in the application. Claims 1, 8, and 22 have been amended. Claims 27-29 are newly added. Claims 15-17 were withdrawn from consideration as being drawn to a nonelected species in the previous office action. Newly added claim 29 is withdrawn from consideration as being drawn to a nonelected species. Claims 1-14, 18-20, and 22-28 will presently be examined to the extent they read on the elected subject matter of record.

### **Status of the Claims**

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set of rejections presently being applied to the instant application.

### ***Double Patenting***

Claims 1-2 and 11-14 of this application conflict with claims 19-20 and 40 of U.S. Patent Application Publication No. 2001/0018070, now US Patent No. 6,340,475. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during

pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 11-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-20 and 40 of U.S. Patent No. 6,340,475. Although the conflicting claims are not identical, because they are not patentably distinct from each other because both applications are directed towards a method of delivering a pharmacologically active agent by orally administering to a patient in the fed mode a therapeutically effective amount of the active agent and at least one biocompatible, hydrophilic polymer that swells upon absorption of water from gastric fluid in order to promote gastric retention. In the instant claims, the dosage form is a matrix/active agent tablet, wherein the active is ciprofloxacin. Claim 19 in U.S. Patent No. 6,340,475 does not provide for a matrix/active agent tablet dosage, however, it would have been obvious to one skilled in the art that the drug would have been dispersed in a polymeric matrix that is water-swellable rather than merely hydrophilic and that has an erosion rate that is substantially slower than its swelling rate, and that releases the drug primarily by diffusion, as taught in the specification. Therefore, the scopes of the copending claims overlap and thus they are obvious variants of one another.

***Allowable Subject Matter***

Claims 3-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims are free of the prior art. The closest prior art, Shell et al. (U.S. 5,972,389), teaches administering a plurality of particles, which are specifically designed to rapidly fall apart upon administration. Shell et al. teaches when the dosage is in the form of a tablet or capsule, the form would rapidly dissolve or disintegrate upon contact with the gastric fluid to permit the particles to quickly disperse in the stomach. Shell et al. does not suggest or teach a method of administering a dosage form that maintains its size for an extended period of time before it is diminished by erosion.

Claims 18-20 and 22-28 are allowed. The following is a statement of reasons for the indication of allowable subject matter: The claims are free of the prior art. The closest prior art, Shell et al. (U.S. 5,972,389), teaches administering a plurality of particles, which are specifically designed to rapidly fall apart upon administration. Shell et al. teaches when the dosage is in the form of a tablet or capsule, the form would rapidly dissolve or disintegrate upon contact with the gastric fluid to permit the particles to quickly disperse in the stomach. Shell et al. does not suggest or teach a method of treating a human patient suffering from a bacterial infection that is responsive to the oral administration of ciprofloxacin in a dosage form that maintains its size for an extended period of time before it is diminished by erosion.

***Conclusion***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is 571-272-9328. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Andriae M. Holt  
Patent Examiner  
Art Unit 1616

/Johann R. Richter/

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Supervisory Patent Examiner, Art Unit 1616